

**Notice of Allowability**

Application No.

10/501,636

Examiner

Rei-tsang Shiao, Ph.D.

Applicant(s)

CATALANO ET AL.

Art Unit

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on April 23, 2007.
2. ☒ The allowed claim(s) is/are 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52, now are 1-33.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                            |                                                                                                  |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 5. <input type="checkbox"/> Notice of Informal Patent Application                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|                                                                                                            | 9. <input type="checkbox"/> Other _____                                                          |

### **DETAILED ACTION**

1. This application claims benefit of the provisional application: 60/349,812 with a filing date 01/17/2002.
2. Amendment of claims 1 and 47, cancellation of claims 2-4, 18, 20, 22-27, 30-33, 43 and 48-50 in the amendment filed on April 23, 2007, is acknowledged. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 are pending in the application.

### ***Responses to Amendment/Arguments***

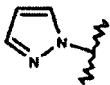
3. The rejection of claims 47 under 35 U.S.C. 112, first paragraph has been overcome, in part, in the amendment filed on April 23, 2007. Since claim 48 has been cancelled, the rejection of claim 48 under 35 U.S.C. 112, first paragraph has been obviated herein.
4. Applicant's arguments regarding the rejection of claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 under 35 U.S.C. 103(a) over Catalano et al. US 2005/ 0043368 A1 or the provisional rejection under the obviousness-type double patenting over the co-pending application No. 10/492,059 filed on April 23, 2007 have been fully considered and they are persuasive. Catalano et al. compounds of formula (I) do not contain three oxo moieties, which are distinct from the instant compounds of formula (I). Therefore the rejection of claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 under 35 U.S.C. 103(a) or under the obviousness-type double patenting over Catalano et al. has been withdrawn herein. Since claim 48 has been cancelled, the rejection of claim

48 under 35 U.S.C. U.S.C. 103(a) or under the obviousness-type double patenting has been obviated herein.

5. Applicant's arguments regarding the provisional rejection of claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 under the provisional rejection under the obviousness-type double patenting over Catalano et al. co-pending application No. 10/510,469 filed on April 23, 2007 have been fully considered and they are persuasive. Since the instant variable D of compounds of formula (I) is distinct from Catalano et al. compounds of formula (I), therefore the rejection of claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 under the obviousness-type double patenting over Catalano et al. has been withdrawn herein. Since claim 48 has been cancelled, the provisional rejection of claim 48 under the obviousness-type double patenting has been obviated herein.

#### **EXAMINER'S AMENDMENT**

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Kathryn L. Coulter on May 30, 2007. The application has been amended as follows:



In claim 21, line 5, after "  ", delete ";

In claim 47, line 4, delete "atherosclerosis, and neoplastic diseases associated with cathepsin K activity", and insert  
--and atherosclerosis--

### ***Reasons for Allowance***

7. The following is an examiner's statement of reasons for allowance:

Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to cycloalkyl ketoamides derivatives useful as cathepsin k inhibitors. The closest prior art is Powers' US 6,235,929, discloses tripeptide alpha-ketoamides. The difference between the reference and instant claims is that instant claimed compounds of formula (I) have not been found. A suggestion for modification of above reference to obtain the instant compounds/compositions and methods of use has not been found. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-47 and 51-52 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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PATENT EXAMINER

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May30, 2007